Support for Amendments:

Claims 9 and 13 were amended to incorporate a requirement that the capsule be made of materials that are pharmaceutically acceptable with respect to their chemical and physical properties. Support for this amendment is found on at least page 1, lines 7-9.

The amendments do not add new subject matter.

REMARKS/ARGUMENTS

102(b) Rejection

The pending office action rejected Claims 9, and 13-14 based on 35 U.S.C. 102(b), alleging that said claims were anticipated by Ogi (USPN 4155478). It was alleged that Ogi teaches the claimed inventions as evidenced by the entire specification and fig 1, noting that casing 1 constitutes a capsule, and the mold of Ogi constitutes the claimed sealing clamp that clamps and holds the capsule and further noting that the injection mold inherently has injection ports.

Applicant respectfully traverses the 102(b) rejection.

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1063 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) (claim to a system for setting a computer clock to an offset time to address the Year 2000 (Y2K) problem, applicable to records with year date data in "at least one of two-digit, three-digit, or four-digit" representations, was held anticipated by a system that offsets year dates in only two-digit formats). See also MPEP2131.02 "The identical invention must be shown in as complete detail as is contained in the claim." *Richland v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1931, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Note that, in some circumstances, it is permissible to use multiple references in a 35 U.S.C. 102 rejection. See MPEP § 2131.01. [MPEP 2131.]
>
> During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.' The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir.

2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:

> The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1).

[MPEP 2111]

> During examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004) (The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation in light of the specification.). This means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. [MPEP 2111.01 (I), references omitted.]

"The ordinary and customary meaning of a term may be evidenced by a variety of sources, including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips v. AWH Corp.*, 415 F.3d at 1314, 75 USPQ2d at 1327. If extrinsic reference sources, such as dictionaries, evidence more than one definition for the term, the intrinsic record must be consulted to identify which of the different possible definitions is most consistent with applicant's use of the terms. MPEP 2111.01 (III), references omitted.

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert,* 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a

given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) . . . .

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.). [MPEP 2112, IV, emphasis in original.]

The essential elements of Claim 9 are:

(1) sealing a hard shell capsule that:

(a) has coaxial body parts which overlap when telescopically joined, and

(b) is made of materials that are pharmaceutically acceptable with respect to their chemical and physical properties.

(2) the sealing process comprises:

(a) using a sealing clamp to clamp and hold the capsule in a precise and upright position,

(b) injecting a quantity of sealing fluid in the overlap of the telescopically joined body parts; and

(c) releasing the capsule.

In order for materials to be pharmaceutically acceptable with respect to their chemical and physical properties, they must be of a composition and shape to allow use by a mammal, e.g., a human, dog, cat, cow, pig, etc. This does not mean that the capsules are limited to active pharmaceutical ingredients; to the contrary, the capsules are to be composed of material to hold anything that is intended for use in a mammal; for example, an active pharmaceutical ingredient, vitamin supplement(s), etc. The key aspect is that the capsule of

the pending invention must be made of such material and be of such a shape to allow delivery to a mammal.

Furthermore, the method involves the tightening effect applied by the sealing clamp to the capsule, the zone of distribution of the sealing fluid is, therefore, more limited to the overlap. This allows a more precise application of the sealing fluid in the overlap, so a specified volume of sealing fluid is applied. It should be noted that the injection ports direct sealing fluid to overlap of the capsule. The sealing fluid enters the overlap by capillary action. The overlap is not a confined cavity. It is open on both ends: the end at which the sealing fluid is applied and the end within the capsule. There is no defined cavity into which sealing fluid is injected.

The essential elements of Claim 13 are for an apparatus that:

(1) Seals a hard shell capsule that

(a) has coaxial body parts which overlap when telescopically joined; and

(b) is made of materials that are pharmaceutically acceptable with respect to their chemical and physical properties;

(2) a sealing clamp to clamp and hold the capsule in an upright position; and

(3) a means to inject a sealing fluid in the overlap of the telescopically joined body parts.

Grave error has occurred by stating that the mold in Ogi is like the clamp in the pending application and that the casing in Ogi is like the capsule in the pending application. The pending invention has not been appreciated.

The invention in Ogi relates to the manufacture of **shaped plastic articles from thermoplastic or thermosetting synthetic resin** and in particular to shaped hollow plastic articles having a complicated inner and/or outer shape and also to a method of manufacturing such hollow plastic articles. Ogi, Col. 1, lines 9-14, emphasis added. It is an object of the Ogi invention to provide a new plastic article consisting of separately molded portions and also to provide a new method of manufacturing such a plastic article by providing a **molded joint portion of thermoplastic material** such as polyethylene, polypropylene or the like between the molded portions **by means of injection molding, extrusion molding or the like**. Ogi. Col. 1, lines 43-50, emphasis added. The plastic article according to Ogi's invention comprises at least two separately molded portions and at least one molded joint

portion which is molded in jointing grooves formed between dividing end faces of said molded portions, said molded joint portion and said molded portions being united into one body by fusing at their contact surfaces. Ogi, Col. 2, lines 18-24.

Reference to Figure 1 in the office action further distinguishes Applicant's invention from Ogi. For the following text, please see Ogi, Col 2, line 48 spanning to Col. 3, line 21, emphasis added:

> Figure 1 is a vertical sectional view of an air cleaner casing according to the invention [in Ogi].
>
> . . . .
>
> Referring now to the drawing, FIG. 1 shows an air cleaner casing 1 manufactured in accordance with an embodiment of the present invention. The casing 1 comprises two molded portions which may be separately molded by a conventional molding process and which may be made of polyethylene.
>
> The molded portions 2 and 3 are provided at the dividing stepped end faces 4 and 5 thereof with **grooves 7, 7 and cutouts 8, 8** at the corresponding zones so as to **provide a substantially key-shaped jointing groove (7, 8) extending around the outer periphery of the article and being opened to the outside at an outer peripheral opening 9** when the molded **portions 2 and 3 are assembled by abutting** the dividing end faces 4 and 5 to each other, as is shown in FIG. 1.
>
> The assembled molded portions 2 and 3 **may be inserted into a metal mold, not shown, and then heated and plasticized polyethylene from an injection molding machine or extruding machine, not shown, connected to the metal mold** is injected or forced into the jointing groove 7, 8 through a duct, not shown, in the metal mold and **through an opening 9 opened at the outer periphery 6 of the molded portions 2 and 3** and is cooled and hardened in the jointing groove to provide a molded portion 10 thereat.
>
> **The injected or extruded plastic material may be plasticized by heat and has a temperature sufficient to melt the plastic material of the molded portions 2 and 3 when they are contacted to each other** so that it fuses the plastic material of the molded portions 2 and 3 at their contact surfaces and upon cooling and hardening to provide a molded joint portion 10 which is united with the molded portions 2 and 3 and thereby connects the molded portions rigidly and provides an airtight seal between the **abutting end faces 4 and 5**. [Emphasis added.]

Applicant respectfully draws attention to pages 209-215 of Chapter 6 of The New Book of POPULAR SCIENCE © 2002. See attached hereto in the Appendix. Chapter 6 concerns technology. Plastics and other polymers are discussed on the referenced pages, including the manufacturing process. In the processes described on pages 212-214, including extrusion molding and injection molding, a mold is used to constrain the shape of the melted plastic forced into said mold. In injection molding, the pressure with which the plastic is

injected into the mold is stated to be up to 30,000 pounds per square inch. In Ogi, the joint is a molded part.

Furthermore, also see definitions within McGraw-Hill Dictionary of Scientific and Technical Terms, attached hereto in the Appendix:

Injection Molding is defined: "Molding metal, plastic, or non-plastic ceramic shapes by injecting a measured quantity of the molten material into dies." [Page 1079]

Extrusion, with regard to engineering, is defined: "A process in which a hot or cold semisoft solid material, such as metal or plastic, is forced through the orifice of a die to produce a continuously formed piece in the shape of the desired product." [Page 769]

Die, with regard to engineering, is defined: "A tool or mold used to impart shapes to, or to form impressions on, materials such as metals and ceramics." [Page 595]

Mold, with regard to engineering, is defined: "A pattern or template used as a guide in construction" or "A cavity which imparts its form to a fluid or malleable substance." [Page 1362].

With these general principles of thermoplastics, which is what Ogi concerns, the mold in Ogi should not be found to be a clamp, and the casing in Figure 1 should not be found to be the capsule in the pending invention. This is especially so for purposes of patentability under 35 USC 102(b).

No molding occurs in Applicant's invention. The clamp clamps and holds the capsule and the injection ports direct **sealing fluid** to the overlap of the capsule. The sealing fluid enters the overlap. The injection port(s) directs sealing fluid to the opening of the overlap, but there is no confined cavity into which the sealing fluid goes and the sealing fluid does not assume any shape because there is no cavity as occurs in Ogi with the key joint.

Ogi does not anticipate Applicant's invention for at least the following reasons:

(1) The capsule in Applicant's invention has coaxial body parts which overlap when telescopically joined. The container in Ogi has non-overlapping, abutting parts that make a key joint.

(2) The capsule in Applicant's invention is made of materials that are pharmaceutically acceptable with respect to the chemical and physical properties. The container in Ogi is made of thermoplastic material that is not physiologically compatible. Figure 1 concerns a container that is an air cleaner casing.

(3) The casing in Ogi makes a key joint into which thermoplastic material is placed to melt the two parts making the molded-key joint. The key joint is surrounded on all sides

except for the inlet into which thermoplastic material is forced. The capsule in the pending application is formed from sealing fluid going into the overlap of two coaxial body parts by capillary action; please note, the overlap does not have a confined cavity.

(4) By comparing the casing and mold in Ogi to the capsule and clamp, respectively, in the pending invention, the general principles of injection molding and extrusion molding are not appreciated. See, e.g., material in the Appendix attached hereto and discussed above.

(5) Last, but not least, inherency is relied upon to say the alleged clamp in Ogi has injection ports. The minimum requirements to rely upon inherency for this rejection have not been satisfied. The burden should not be found to have shifted to Applicant and anticipation should not be found based on inherency:

> First, Ogi shows no clamp. Ogi discussed a metal mold, but there is no description of what this mold is. As already discussed, a mold used in connection with injection molding and extrusion molding is completely irrelevant for Applicant's invention.
>
> Second, the mold appears to then be heated and plasticized polyethylene is then injected or forced into the key joint. There is no description of exactly how the plasticized polyethylene is placed in the key joint. Ogi fails to "make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." MPEP 2112. Ogi does not even describe any clamp but makes mere reference to a metal mold. There is no description how this mold used in connection with injection molding and extrusion molding could be a clamp as used in Applicant's invention.

The alleged clamp in Ogi does not anticipate Applicant's invention. First, there is no clamp described in Ogi. It is Applicant's position that the pending office action does not sufficiently describe the similarities between the reference and Applicant's invention to find the claims anticipated. However, to try to be as responsive as possible, while not waiving this argument, Applicant continues to respond to this rejection.

There is a general reference with regard to Figure 1, stating that a clamp may be used—there is no clamp required and no clamp described. Not only is the clamp not described, the differences in the sealing process are not appreciated. The alleged clamp from Ogi is attached to an injection molding machine or extruding machine that injects or forces

plasticized polyethylene into an opening on the outer periphery of the abutted portions. Furthermore, the container parts are heated during the injection process and there is nothing discussing how the container is held during the injection process. The injected or extruded plastic material may be plasticized by heat and has a temperature sufficient to melt the plastic material of the molded portions.

Applicant's clamp is used to seal capsules that are coaxial joined body parts which overlap when telescopically joined and that are made of pharmaceutically acceptable materials with respect to their chemical and physical properties. The clamp clamps and holds the capsule in an upright position and injects a sealing fluid in the overlap of the body parts.

Assuming, arguendo, that the prior art device performs all the functions recited in the claim, the prior art cannot anticipate the claim if there is any structural difference. It should be noted, however, that means plus function limitations are met by structures which are equivalent to the corresponding structures recited in the specification. MPEP 2114, citations omitted. The Ogi reference is completely silent on any technical features of the alleged clamp used. However, technical features of Applicant's invention are described such that the clamp clamps and holds capsules that have coaxial body parts which overlap when telescopically joined; are made of materials that are pharmaceutically acceptable with respect to their chemical and physical properties; and clamp and hold each capsule in a vertical position with regard to the means to inject the sealing fluid. Therefore, Ogi cannot anticipate Applicant's invention.

Applicant respectfully requests withdrawal of the 102(b) rejection.

103(a) Rejection

The pending office action rejects Claims 10-12 under 35 U.S.C. 103(a) as being unpatentable over Ogi (USPN 4155478), incorporating the allegations made under the 102(b) rejection.

In regard to claim 10, the office action alleges that such is well-known in the molding art in order to provide a presentable final product. Thus, it was alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove any flash on the outside of the capsule in order to provide a presentable final product. In regard to claims 11-12, it was alleged that such is well-known in the molding art to remove

flash from a molding apparatus in order to prepare for another molding cycle. Thus, it was alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove flash from the mold/clamp of Ogi in order to prepare the mold/clamp for another molding cycle.

The pending office action also rejects Claims 15-17 under 35 U.S.C. 103(a) as being unpatentable over Ogi (USPN 4155478), incorporating the allegations made under the 102(b) rejection. In regard to claim 15, the office action states that recycle means within molds are well-known in the molding art in order to reduce manufacturing costs; thus, it was alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to include liquid recovery grooves in the apparatus of Ogi in order to achieve the above result. In regard to claim 16, the office action states that molds having airing and suction ports are well-known in the molding art in order to efficiently fill a mold cavity; thus, it was alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an airing and a suction port in apparatus of Ogi in order to achieve the above result. In regard to claim 17, the office action states that the specific design of the mold groove/cavity is a mere obvious matter of choice dependent on the desired final product and of little patentable consequence to the claimed apparatus since it is not a manipulative feature or step of the claimed apparatus; further, it was alleged that molds having injection grooves are well-known in the molding art; thus, it was alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to design the apparatus of Ogi to have the claimed groove in order to form an article having a protruding band.

Applicant respectfully traverses the 103(a) Rejection. Applicant believes that the procedural and substantive requirements to support the 103 rejection have not been and cannot be satisfied. Applicant also maintains the position that Ogi is non-analogous art and that it fails to describe Applicant's invention when the terms are given their plain meaning and read in light of the whole specification.

As stated in Applicant's response to the Office Action mailed November 1, 2007, the USPTO provided guidelines regarding obviousness rejections following the decision of *KSR*

Int'l Co. v. Teleflex, Inc., No 04-1350 (U.S. Apr. 30, 1997). Federal Register, Vol. 72, No. 195, 10/10/2007, page 57526. The notice states, in pertinent part:

> Once the *Graham* factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art.
>
> . . . .
>
> . . . . The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. [*Id*., 57528-57529.]
>
> Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court [in *Graham v. John Deere Co.*,383 U.S. 1, 148 USPQ 459 (1966)] are as follows:
>
> (1) Determining the scope and content of the prior art;
>
> (2) Ascertaining the differences between the claimed invention and the prior art; and
>
> (3) Resolving the level of ordinary skill in the pertinent art.
>
> Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel. . . .
>
> The question of obviousness must be resolved on the basis of these factual determinations. While each case is different and must be decided on its own facts, the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis. . . . .
>
> . . . .
>
> Office personnel fulfill the critical role of factfinder when resolving the *Graham* inquiries. It must be remembered that while the ultimate determination of obviousness is a legal conclusion, the underlying *Graham* inquiries are factual. When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. . . . . Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.
>
> Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103. 35 U.S.C. 132 requires that the applicant be notified of the reasons for the rejection of the claim so that he or she can decide how best to proceed. Clearly setting forth findings of fact and the rationale(s) to support a rejection in an Office action leads to the prompt resolution of issues pertinent to patentability.

> In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense. What follows is a discussion of the *Graham* factual inquiries. [*Id.* at 57527, citations omitted.]

These passages can only be taken to mean that a *Graham* factual analysis is a necessary first step of every rejection based on obviousness and that the factual analysis must be articulated on the record. This was not done in the pending office action.

More importantly, all conclusory statements made in support of the pending rejections are based on molding technology. Applicant incorporates herein all arguments raised when responding to the 102(b) rejection to establish that molding technology is not pertinent to the pending invention.

In further support of Applicant's traverse, Applicant takes exception with reliance on removal of flash in support of the 103 rejections that such a process would make the rejected claims obvious. "In plastics and rubber molding or in metal casting, [flash is] that portion of the charge which overflows from the mold cavity at the joint line." McGraw-Hill, page 814. In the pending invention, there is no defined joint cavity and there is no joint line. Moreover, it is Applicant's position that in injection molding, the "flash" would be solid. See, e.g., Popular Science, *supra*, page 213, wherein it is discussed that the mold is filled and the plastic cooled and becomes a solid. From the perspective of a capsule in the pending invention where there are capsule parts that are coaxially-joined, overlapped parts, the technology to remove solid "flash" is completely different and unrelated to the removal of liquid sealing fluid from a capsule as described in the pending invention where there is an overlap in which sealing fluid enters by capillary action.

Applicant challenges the use of Ogi as non-analogous art. The MPEP states at 2141.01(a), Section I:

> The examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

> A prerequisite to making this [obviousness] finding is determining what is "prior art," in order to consider whether "the differences between the subject matter sought to be patented and the prior art are such that **the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art**." 35 U.S.C Section 103. Although Section 103 does not, by its terms, define the "art to which [the] subject matter [sought to be patented] pertains," this determination is frequently couched in terms of whether the art is analogous or not, i.e. , whether the art is "too remote to be treated as prior art." In re Sovish, 769 F.2d 738, 741, 226 USPQ 771, 773 (Fed.Cir. 1985). [*In re Clay*, 966 F.2d 656; 23 USPQ2d 1058, 1060 (Fed. Cir. 1992), emphasis added.]

In *Clay*, the invention was a process for storing refined liquid hydrocarbon product in a storage tank having a dead volume between the tank bottom and its outlet port. Two prior art references were cited. The court in *Clay* discussed the two factors both Applicant and Examiner have cited for evaluation of whether the references were proper. The court determined that the references were not within the same field and that the references were not proper because the problems to be solved were not reasonably pertinent to the problem of Clay's invention:

> Even though the art disclosed in [the] Sydansk [reference] is not within Clay's field of endeavor, the reference may still properly be combined with Hetherington if it is reasonably pertinent to the problem Clay attempts to solve. *In re Wood*, 599 F.2d at 1036, 202 USPQ at 174. A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it. [Id. at 1060-1061, emphasis added.]

See also, Fed. Reg., Vol. 27, No 195, p 57528, citing MPEP 2141.02.

Like in *Clay*, the problem solved by the pending invention is different from the problem solved by the reference (Ogi).

Applicant incorporates herein all arguments provided *supra* when responding to the 102(b) rejection based on Ogi. A problem to be solved has not been asserted with regard to the Ogi reference to show its appropriateness as a reference. In Ogi, the problem is to

provide a new plastic article consisting of separately molded portions and also to provide a new method of manufacturing such a plastic article by providing a molded joint portion of thermoplastic material such as polyethylene, polypropylene or the like between the molded portions by means of injection molding, extrusion molding or the like. See Ogi, col. 1, lines 43-50.

However, the pending invention concerns sealing hardshell, coaxial, telescopically-joined body parts made of pharmaceutically acceptable material by injecting sealing fluid in the overlap of the joined body parts. Therefore, to solve the problem solved by Applicant's invention, one of ordinary skill in the art of capsule development for use in mammals would not look to technology for making molded products sealed by a molded joint using thermoplastic material.

Inappropriate hindsight has been used to mold the problem and to allege that Ogi is relevant. The problems to be solved in Ogi are completely different than the problems facing the inventors of the pending invention. Therefore, Ogi should not be found to be analogous art.

Last, assuming, *arguendo*, that Ogi is found to be analogous art, and this is not an acceptance of Ogi as a proper reference, Applicant contends that obviousness has not and cannot be established when the pending invention is appreciated in light of the specification and claims.

Applicant incorporates herein the arguments previously made herein regarding how the process and product in Ogi concerns a key-molded material, molded by molded portions. Because of the discussion *supra*, it is Applicant's position that Ogi does not make Applicant's invention obvious where Applicant's invention concerns a method and an apparatus for sealing a hard shell capsule having coaxial body parts which overlap when telescopically joined where sealing fluid is injected in the overlap. The method was previously described and is incorporated herein. The apparatus comprises:

(1) a sealing clamp to clamp and hold the capsule in an upright position; and

(2) injection port(s) to inject a sealing fluid in the overlap of the body parts.

As discussed already, Ogi fails to at least describe injection of a sealing fluid in the overlap formed from coaxial, telescopically-joined body parts. Therefore, Ogi should not be found sufficient to make Applicant's invention obvious.

Moreover, the obviousness rejection concerns claims 15-17. Applicant is unable to locate in Ogi where the limitations of these claims are discussed. The pending Office Action also fails to comply with *KSR* and the new guidelines for rejecting claims based on 103. If the claims are not allowed, Applicant respectfully requests a thorough *Graham* factor analysis regarding Ogi alone and in any combination with the references regarding the state of the art.

Applicant respectfully requests the withdrawal of the 103(a) rejection for claims 10 to 12 and 15 to 17. If the rejection is not withdrawn, Applicant requests a thorough *Graham* factual analysis, including an affidavit from the Examiner to the extent that the Examiner relies on his personal knowledge for the basis of the 103 rejection. 37 C.F.R. 1.104(d)(2). And, as previously requested, if the rejection is not withdrawn, Applicant requests specific citations to the "well-known" technology referenced in the rejection to allow Applicant an opportunity to review any references, including a thorough *Graham* analysis of each. 37 CFR 1.104, specifically, but not limited to, 37 CFR 1.104(c)(2).

Address Change Form

Included with this response is an Address Change Form, PTO/SB/122. Please direct all future correspondence to the address associated with Customer Number 28523. This case is being transferred to the docket of Carl J. Goddard, Registration No. 39203.

Conclusion

Applicant believes that the claims are in order for allowance, early notice of which is requested. If Examiner has any questions concerning this application, Examiner is invited to contact Carl Goddard at (860) 441-4902. A three-month extension fee is due. Please charge any payment or credit any overpayment to Charge Account 16-1445.

Respectfully submitted,

/Mary J. Hosley/ Date: 29 October 2008

Mary J. Hosley, Attorney, Registration No. 48,324
Attorney for Applicant
Pfizer, Inc
150 East 42nd Street, Floor 5
New York, NY 10017-5612
Telephone No. 212.733-0460; Telefax No. 212.573-1939